

Vaccine News and Previews

Part 1

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Disclosures

- The speaker is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation
- The speaker will discuss the off-label use of Tdap and pneumococcal conjugate vaccines
- The speaker will not discuss a vaccine not currently licensed by the FDA

Objectives

- Increase provider knowledge regarding immunizations and the importance of promoting immunizations in the community.
- Explain at least one recent change to immunization recommendations from the Advisory Committee on Immunization Practices (ACIP)

Overview

- 2012 schedules
- Hepatitis B for adults with diabetes mellitus
- Rotavirus vaccine successes
- Tdap vaccine for children 7-10 years of age, pregnant women, and persons 65 years and older
- PCV13 supplemental dose

Immunization Recommendations

- The recommendations to be discussed are primarily those of the Advisory Committee on Immunization Practices (ACIP)
 - composed of 15 experts in clinical medicine and public health who are not government employees
 - provides guidance on the use of vaccines and other biologic products to the Department of Health and Human Resources, CDC, and the U.S. Public Health Service

www.cdc.gov/vaccines/recs/acip/

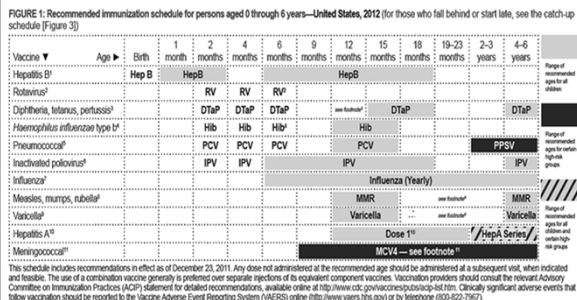
Schedule Changes for 2012

- Vaccination providers are being advised to use all three schedules and their respective footnotes together and not separately
- Redundant footnotes across 3 schedules placed on only 1 schedule

Changes to 2012 Childhood Schedule

- MCV4 purple bar extended to reflect licensure of MCV4-D (Menactra) use in children as young as age 9 months
- Wording change in HepA yellow bar - "Dose 1." A new yellow and purple bar added to reflect HepA recommendations for children aged 2 years and older
- Footnote Changes
 - HepB
 - Hib
 - RV
 - PCV
 - HepA
 - MMR
 - MCV4
 - Flu

2012 Childhood Schedule Persons aged 0 through 6 years



www.cdc.gov/vaccines/recs/schedules/downloads/child/0-6yrs-schedule-pr.pdf

Changes to 2012 Adolescent Schedule

- Number of doses for each vaccine included
- Information regarding the recommended age (16 years) for MCV4 booster dose added
- Tdap vaccine recommendations for children aged 7 through 10 years updated
- Footnote Changes
 - HPV
 - VAR
 - IPV

2012 Adolescent Schedule

Persons aged 7 through 18 years

FIGURE 2. Recommended immunization schedule for persons aged 7 through 18 years—United States, 2012 (for those who fall behind or start late, see the schedule below and the catch-up schedule (Figure 3))

Vaccine	Age	7–10 years	11–12 years	13–18 years	Range of recommended ages for all doses
Tetanus, diphtheria, pertussis ¹		1 dose (if indicated)	1 dose	1 dose (if indicated)	
Human papillomavirus ²		See footnote ³	3 doses	Complete 3-dose series	
Meningococcal ⁴		See footnote ³	Dose 1	Booster at 16 years old	
Influenza ⁵		Influenza (yearly)			
Pneumococcal ⁶		See footnote ³			
Hepatitis A ⁷		Complete 2-dose series			
Hepatitis B ⁸		Complete 3-dose series			
Inactivated poliovirus ⁹		Complete 3-dose series			
Measles, mumps, rubella ¹⁰		Complete 2-dose series			
Varicella ¹¹		Complete 2-dose series			

This schedule includes recommendations in effect as of December 23, 2011. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/imz/immunization-practices>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.hhs.gov>) or by telephone (800-822-7967).

www.cdc.gov/vaccines/recs/schedules/downloads/child/7-18yrs-schedule-pr.pdf

Childhood Catch-up Schedule

FIGURE 3. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind—United States—2012. The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with the accompanying childhood and adolescent immunization schedules (Figures 1 and 2) and their respective footnotes.

Persons aged 4 months through 5 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B	Birth	4 weeks	8 weeks		
Rotavirus ¹	6 weeks	4 weeks	at least 10 weeks after first dose; minimum age for first dose is 14 weeks		
Diphtheria, tetanus, pertussis ²	6 weeks	4 weeks	4 weeks	6 months	6 months ³
Hemophilus influenzae type B ⁴	6 weeks	4 weeks	8 weeks	8 weeks (as first dose) ⁵	8 weeks (as first dose) ⁵
Pneumococcal ⁶	6 weeks	4 weeks	8 weeks	8 weeks (as first dose) ⁷	8 weeks (as first dose) ⁷
Inactivated poliovirus ⁸	6 weeks	4 weeks	4 weeks	4 weeks (as first dose) ⁹	4 weeks (as first dose) ⁹
Meningococcal ¹⁰	9 months	8 weeks ¹¹			
Measles, mumps, rubella ¹²	12 months	4 weeks			
Hepatitis A	12 months	6 months			

www.cdc.gov/vaccines/recs/schedules/downloads/child/catchup-schedule-pr.pdf

Adolescent Catch-up Schedule

Persons aged 7 through 18 years					
Tetanus, diphtheria/tetanus, diphtheria, pertussis ¹	7 years ²	4 weeks	4 weeks	6 months	
Human papillomavirus ³	9 years		6 months	if first dose administered at younger than age 12 months	
Hepatitis A	12 months	6 months	6 months	if first dose administered at 12 months or older	
Hepatitis B	Birth	4 weeks	8 weeks	8 weeks	
Inactivated poliovirus ⁴	6 weeks	4 weeks	4 weeks	4 weeks	
Meningococcal ⁵	9 months	8 weeks ⁶			
Measles, mumps, rubella ⁷	12 months	4 weeks			
Varicella ⁸	12 months	3 months	4 weeks		

www.cdc.gov/vaccines/recs/schedules/downloads/child/catchup-schedule-pr.pdf

Changes to 2012 Adult Schedules

- Age-based schedule
 - 19-26 y/o age group split into 2 groups 19-21 and 22-26 related to HPV recommendations for males
 - Td/Tdap hashed bar for 65 years and older
 - HPV bar separated for females and males
- Risk-based schedule
 - MSM column added
 - Diabetes indication moved to same column as chronic kidney disease for HepB recommendation
 - Td/Tdap yellow bar extended to include pregnant women
 - HPV yellow bar separated for females and males.
 - Female bar: Extended to include HCP to clarify HPV indicated if HCP in recommended age group.
 - Male bar: Indicates vaccination through age 26 for HIV+, immunocompromised, or MSM. However, the age indication is through age 21 for males with or without these risk factors
 - Red contraindication bar added to legend
- Table summarizing precautions and contraindications added

Changes to 2012 Adult Schedules

- Footnote changes
 - A new footnote to links for the full ACIP vaccine recommendations and where to find additional information on specific vaccine recommendations for travelers
- Flu
- HPV
- ZOS
- MMR
- PPSV23
- MCV4/MPSV4
- HepB

2012 Age-based Adult Schedule

Persons aged 19 years and older

Recommended Adult Immunization Schedule—United States - 2012

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group*

VACCINE ▼	AGE GROUP ►	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza [†]							
Tetanus, diphtheria, pertussis (Td/Tdap) ^{†*}							
Varicella ^{**}							
Human papillomavirus (HPV) Female ^{†*}							
Human papillomavirus (HPV) Male ^{†*}							
Zoster [†]							
Measles, mumps, rubella (MMR) ^{†*}							
Pneumococcal (polysaccharide) ^{**}							
Meningococcal ^{**}							
Hepatitis A ^{†*}							
Hepatitis B ^{†*}							

Covered by the Vaccine Injury Compensation Program: ☐ Not recommended if contraindication exists. ☐ Recommended if contraindication exists. ☐ Recommended if contraindication exists. ☐ Recommended if contraindication exists. ☐ Recommended if contraindication exists.

Report all clinically significant adverse reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions are available at www.vaers.hhs.gov or by telephone, 800-332-7372.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hhs.gov/vaccineinjurycompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-4400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or through the CDC-INFO Contact Center at 800-CDC-INFO (246-223-4636) in English and Spanish, 9:00 a.m. - 5:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

<http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/adult-schedule.pdf>

2012 Risk-Based Adult Schedule

Persons aged 19 years and older

Figure 2. Vaccines that might be indicated for adults based on medical and other indications¹

Figure 2. Vaccines and their origin for use in adults based on historical safety data and contraindications							
VACCINE ▼	INDICATION ►						
	Pregnancy	Infants < 6 months	Infants 6 months to 12 years	Adolescents > 12 years	Adults	Elderly	Health-care personnel
Influenza	1 dose Td annually	1 dose Td annually	1 dose Td annually	1 dose Td annually	1 dose Td annually	1 dose Td annually	1 dose Td annually
Tetanus, diphtheria, pertussis (Td/Tdap)	Substitute 1 time dose of Tdap for Td booster; then boost with Td every 10 yrs						
Varicella	Contraindicated	Contraindicated	2 doses	2 doses	2 doses	2 doses	2 doses
Human papillomavirus (HPV) Female	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs
Human papillomavirus (HPV) Male	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 21 yrs	3 doses through age 21 yrs	3 doses through age 21 yrs	3 doses through age 21 yrs
Zoster	Contraindicated	Contraindicated	1 dose	1 dose	1 dose	1 dose	1 dose
Measles, mumps, rubella (MMr)	Contraindicated	Contraindicated	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses
Pneumococcal (polysaccharide)	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses
Meningococcal	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses
Hepatitis B	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses

*Covered by the Vaccine Injury Compensation Program

[illegible]

<http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/adult-schedule.pdf>

Adult Contraindications & Precautions

[illegible]

<http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/adult-schedule.pdf>

Hepatitis B

www.cdc.gov/vaccines/pubs/ACIP-list.htm#hepb

www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf

www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf

www.immunize.org/askexperts/experts_hepb.asp

HepB Vaccine in Adults with DM

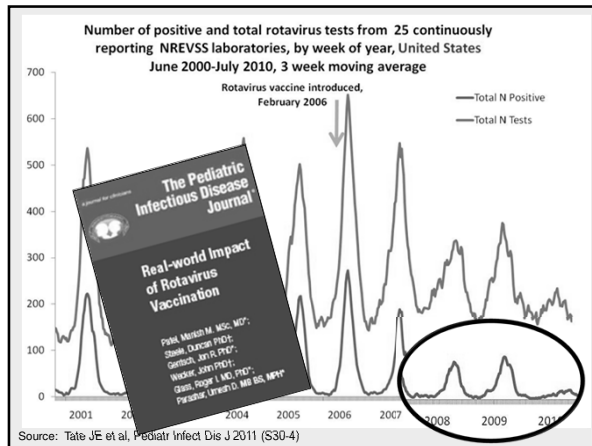
- Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years
- Hepatitis B vaccination may be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged ≥60 years

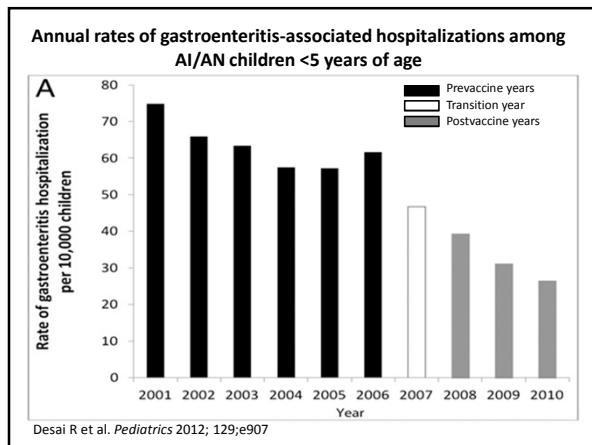
Test Your Knowledge

- A 5-year old received the birth dose of HepB vaccine followed by Pediarix at 2 mos., 4 mos., and 5 mos. 19 days of age (24 wks).
—Does this child need another dose of HepB vaccine?

Rotaviirus

www.cdc.gov/vaccines/pubs/ACIP-list.htm#rotavirus
www.cdc.gov/vaccines/pubs/pinkbook/downloads/rota.pdf
www.cdc.gov/vaccines/pubs/vis/default.htm#rota
www.immunize.org/askexperts/experts_rota.asp





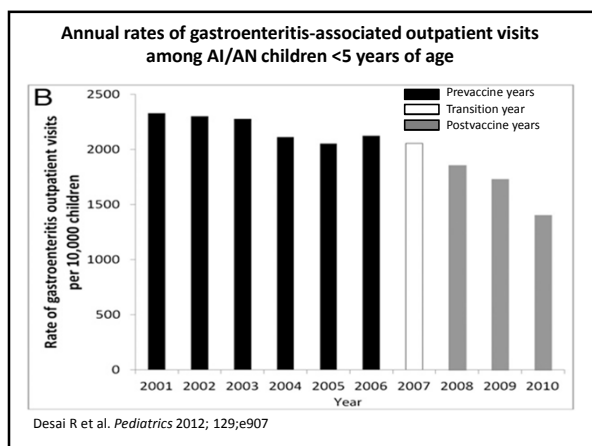


TABLE 4 Expected and Observed Gastrointestinal Hospitalizations and Rates (per 10 000) Among AI/AN Children <5 Years of Age, 2008–2010

	Fiscal Year 2008 ^a			Fiscal Year 2009			Fiscal Year 2010		
	Expected Rate (95% CI) ^b	Observed Rate	Reduction, %	Expected Rate (95% CI) ^b	Observed Rate	% Reduction	Expected Rate (95% CI) ^b	Observed Rate	Reduction, %
Total	52 (48–56)	39	25	50 (45–55)	31	38	48 (42–53)	27	44
Gender									
Boy	58 (53–64)	41	29	56 (50–62)	38	32	53 (47–60)	31	42
Girl	45 (41–50)	38	16	43 (39–48)	25	42	42 (37–47)	22	48
Age group, y									
<1	194 (178–211)	140	28	184 (167–204)	115	38	176 (156–198)	103	41
1–4	24 (22–26)	17	29	23 (20–25)	14	39	21 (19–24)	12	43

CI, confidence interval.

^a HS Inpatient/Contract Health Services inpatient data fiscal years 2001–2009 National Patient Information Reporting System, Albuquerque, NM, HS, 2011.^b Expected rates based upon prevacine secular annual rate of decline of 4.4% (P < .001).Desai R et al. *Pediatrics* 2012; 129:e907

Pertussis

www.cdc.gov/vaccines/pubs/ACIP-list.htm#tdap

www.cdc.gov/vaccines/pubs/pinkbook/downloads/dip.pdf

www.cdc.gov/vaccines/pubs/pinkbook/downloads/tetanus.pdf

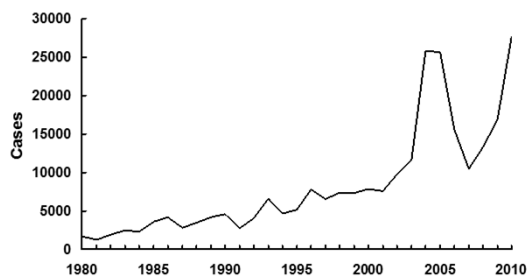
www.cdc.gov/vaccines/pubs/pinkbook/downloads/pert.pdf

www.cdc.gov/vaccines/pubs/vis/downloads/vis-dtap.pdf

www.cdc.gov/vaccines/pubs/vis/downloads/vis-td-dtap.pdf

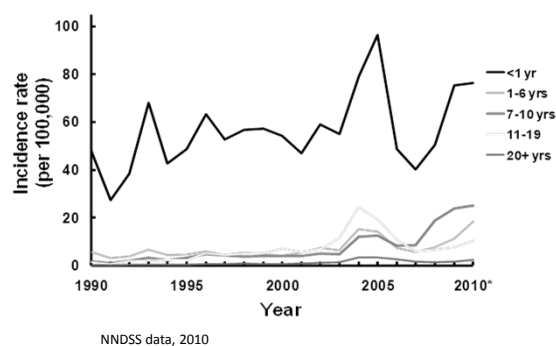
www.immunize.org/askexperts/experts_per.asp

Pertussis - United States, 1980-2010



NNDSS data, 2010

Reported Pertussis Incidence by Age Group - 1990-2010*



Reported Pertussis-related Deaths by Age Groups, U.S., 1980-2010*

Age-Group	1980-1989 ¹	1990-1999 ¹	2000-2010 ²
0-1 month	38	68	170
2-3 month	11	16	28
4-5 month	5	5	2
6-11 month	7	4	1
1-4 years	13	2	3
5-10 years	1	6	3
11-18 years	0	0	3
>18 years	1	2	11
Total	77 ²	103	221

*Provisional 2010 data ¹ Includes one case with unknown age

¹ Vitek CR et al. *Pediatr Infect Dis J* 2003; 22(7):628-34.

² National Notifiable Diseases Surveillance System, CDC.

Tdap

- Tdap reduces the risk of pertussis by 60% - 80%
- Both Tdap products currently approved for one lifetime dose
- Tdap approved ages
 - 10 years and older for Boostrix
 - 11 through 64 years for Adacel
- Neither brand of Tdap is approved by the FDA for children 7 years through 9 years and Adacel is not approved for adults 65 years or older

Wei SC et al. *Clin Infect Dis* 2010;51:315-21

Use of Tdap Among Children 7 Through 10 Years of Age

- Children 7 through 10 years of age who are “not fully immunized” against pertussis and who do not have a contraindication to pertussis vaccine should receive a single dose of Tdap*
- Either brand of Tdap may be used
- Do not administer Tdap at age 11-12 years of age for those who received Tdap at ages 7 through 10 years
- Revaccination issue still being evaluated

*off-label recommendation. MMWR 2011; 60 (No. 1):13-5

Tdap Recommendations for Children 7-10 Years of Age

- “Not fully immunized”
 - fewer than 4 doses of DTaP
 - 4 doses of DTaP and last dose was prior to age 4 years

*off-label recommendation. MMWR 2011; 60 (No. 1):13-5

Why Adolescents and Adults Need Pertussis Vaccine

- Pertussis cases increased in the late 1990s and early 2000s
- 2004 – 25,827 pertussis cases, highest recorded since 1959
 - 67% of cases among adolescents or adults
- Severe illness among young infants with pertussis
- Pertussis immunity wanes in 5-10 years

Source of Infection for Infants With Pertussis

- Household contact – 71%
 - Parent – 55% (mother 37%, father 18%)
 - Sibling – 16%
- Non-household contact – 29%
 - Aunt/uncle – 10%
 - Friend/cousin – 10%
 - Grandparent – 6%

N=44 infants ≤6 months of age. *Pediatr Infect Dis J* 2007;26(4):293-9.

Tdap Recommendations for Adolescents

- All adolescents should preferably receive Tdap at the 11 to 12 year-old preventive healthcare visit
- Persons 11 through 18 years of age who have not received Tdap should receive a dose followed by Td booster doses every 10 years
- Administer at the same visit as other indicated vaccines (e.g. MCV, HPV, influenza)

MMWR 2011; 60 (No. 1):13-5

New Tdap Recommendations for Adults*

- For adults 19 years of age and older who previously have not received a dose of Tdap, a single dose of Tdap should be administered
- When feasible use the FDA approved Tdap vaccine for adults 65 years and older Do not miss an opportunity to vaccinate – administer the vaccine that is available

*off-label recommendation. Approved by ACIP February 22, 2012

Tdap Recommendations for Pregnant Women

- Any woman who might become pregnant is encouraged to receive a single dose of Tdap
- Tdap should be administered to pregnant women who have not received a dose
- Vaccinate during third trimester or late in second trimester (after 20 weeks gestation)
- Alternatively, administer Tdap immediately postpartum

MMWR 2011;60(41):1424-6

Td-Tdap Interval Recommendation*

- Tdap can be administered regardless of the interval since the last tetanus and diphtheria containing vaccine
- ACIP concluded that while longer intervals between Td and Tdap vaccination could decrease the occurrence of local reactions, the benefits of protection against pertussis outweigh the potential risk for adverse events
- No booster doses of Tdap recommended at this time
- After receipt of Tdap, persons should continue to receive Td for routine booster vaccination

*off-label recommendation. MMWR: January 14, 2011 / 60(01);13-15

DTaP and Tdap Administration Errors

Error	Action
DTaP given to person 7 years of age or older	Count dose as valid
Tdap given to child younger than 7 years of age as DTaP #1, 2, or 3	Do not count dose; give DTaP now
Tdap given to child younger than 7 years of age as DTaP #4 or 5	Count dose as valid

Test Your Knowledge

- An 8-year-old patient arrives from Botswana without any immunization records. You decide to vaccinate against diphtheria, tetanus and pertussis.
 - Which vaccine would you give this child today and how many doses: DTaP or Tdap or Td?
 - When this child turns 11 years old, do you give any more vaccine against Diphtheria, Tetanus and Pertussis?
- A 14-year-old child received Td vaccine at age 13 years old (his first Td dose ever). He now presents to your office for his annual check up and you do not see evidence of him receiving Tdap vaccine in the past.
 - Can you give Tdap vaccine today?

S. Pneumoniae

www.cdc.gov/vaccines/pubs/ACIP-list.htm#pcv
www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-pcv.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf
www.immunize.org/askexperts/experts_pcv.asp
www.immunize.org/askexperts/experts_ppv.asp

ACIP Recommendations for PCV13 Supplemental Dose

- A single supplemental dose of PCV13 is recommended for children who have received a complete age-appropriate series of PCV7
 - all children 14 through 59 months of age
 - children 60 through 71 months of age with an underlying medical condition (including those who have already received a dose of PPSV)

MMWR 2010;59(No. 6):258-61

TABLE 2. Underlying medical conditions that are indications for pneumococcal vaccination among children, by risk group

Risk group	Condition
Immunocompetent children	Chronic heart disease ^a
	Chronic lung disease ^b
	Diabetes mellitus
	Cerebrospinal fluid leaks
	Cochlear implant
Children with functional or anatomic asplenia	Sickle cell disease and other hemoglobinopathies
	Congenital or acquired asplenia, or splenic dysfunction
Children with immunocompromising conditions	HIV infection
	Chronic renal failure and nephrotic syndrome
	Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation
	Congenital immunodeficiency ^c

Source: Advisory Committee on Immunization Practices, 2010.

^a Particularly cyanotic congenital heart disease and cardiac failure.^b Including asthma if treated with high-dose oral corticosteroid therapy.^c Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).

MMWR 2010;59(No. 6):258-61

ACIP Recommendations for PCV13 Supplemental Dose

- A single dose of PCV13 may be administered to children 6 through 18 *years* of age who are at increased risk for invasive pneumococcal disease*
 - functional or anatomic asplenia, including sickle cell disease
 - HIV infection and other immunocompromising conditions
 - cochlear implant
 - CSF leak

*off-label recommendation. MMWR 2010;59(No. RR-11):1-19

Test Your Knowledge

- A two-year-old male with sickle cell disease presents at your clinic. His immunization record is up-to-date and includes 4 valid doses of PCV7.
 - Does this child need any further pneumococcal vaccination?
 - If yes, how many doses?
 - If more than one dose is indicated, what is the interval between doses?

CDC Vaccines and Immunization Contact Information

- Telephone 800.CDC.INFO
(for patients and parents)
- Email nipinfo@cdc.gov
(for providers)
- Website www.cdc.gov/vaccines/
- Vaccine Safety www.cdc.gov/vaccinesafety/
